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UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/552,839	11/03/95	WANG	0 CELL-16.3

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HM11/1025

EXAMINER

GUZO, P

ART UNIT

PAPER NUMBER

1636

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DATE MAILED: 10/26/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 7/20/98
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three (3) month(s), or ~~thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 37-42, 49-51 and 62-64 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 37-42, 49-51 and 62-64 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftperson's Patent Drawing Review, PTO-948

- ☐ Notice of Informal Patent Application, PTO-152

☒ Attachment on Deposit of Biological Materials  
- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 37-41, 49-51 and 62-64 are provisionally rejected under the judicially created doctrine of double patenting over claims 37-44, 46-50, 52 and 56-57 of copending Application No. 08/333,680. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both applications recite recombinant adenoviruses comprising lethal deletions or mutations in the E1, E2A and E4 regions, a transgene under control of a promoter of choice; DNA plasmids comprising an inducible promoter (i.e. from mouse alpha inhibin, cAMP response element, etc.) operatively linked to a cytotoxic gene product of the E4 and/or E2A

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regions and packaging cells derived from the 293 cell line that support growth of said recombinant adenoviruses.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claim 62 is rejected under 35 U.S.C. 102(e) as being anticipated by Gregory et al.

Applicants claim a recombinant adenoviral vector comprising at least a lethal deletion in at least two regions selected from the E1, E2A, E4 regions, viral structural genes, etc., a transgene under control of the human PGK promoter and wherein the adenovirus requires complementation of the E1 and E4 regions for replication.

Gregory et al. (U.S. Patent 5,670,488, see whole document, particularly Fig. 16A and 16B;

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column 12, lines 7-50; column 43, line 5 to column 44, line 34 and Example 15) discloses PAV vectors and adenoviruses in which the only adenoviral sequences present are the ITRs and packaging sequence and a transgene in place of the deleted E1, E2A, E3 and E4 regions. Since the instant claims use open claim language and do not preclude the deletion of adenoviral coding sequences other than the regions recited, it must be considered that Gregory et al. teaches the claimed invention.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 42 and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants claim biological material specifically by it's ATCC address and therefore, in order for the skilled artisan to practice the claimed invention, the skilled artisan would need to have unrestricted access to the specific material deposited at the ATCC. A deposit Declaration or

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statement specifying that all restrictions on availability of the deposited materials will be irrevocably removed upon granting of a patent on the instant application is required (See Attachment on Deposits of Biological Materials).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-41, 49-51, 62 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 (and dependent claims) are vague in the recitation of the phrase "...a cAMP response element binding protein regulated genes." since it appears that applicants are referring to a promoter from a cAMP element binding protein regulated gene.

Claims 49, 50, 62 and 63 are vague in that applicants recite E1, E2A, etc. "regions". The metes and bounds of the term "regions" are undefined since it is unclear what other adenoviral sequences in addition to the E1 gene are encompassed in the E1 "region", or what other sequences in addition to the E2A gene are encompassed in the E2A "region", etc.

Claim 51 should begin with "A" rather than "The" and it is unclear whether the ATCC accession number refers to the packaging cell line or the DNA fragment.

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Claim 62 is vague in that it appears to recite improper Markush language in that the members of the Markush group must be linked by "and". In the instant case, the last two members of the Markush are "...E4 early gene regions, viral structural genes..." .

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
October 25, 1998

DAVID GUZO  
PRIMARY EXAMINER  
*David Guzo*